



August 30, 2023

By ECF

Honorable David N. Hurd
Alexander Pirnie Federal Bldg. and U.S. Courthouse
10 Broad Street
Utica, NY 13501

Re: *Dr. A., et al., v. Hochul, et al., 21-CV-1009 (DNH)(ML)*
Status Report

Dear Judge Hurd:

Per Your Honor's directive (ECF 77), Plaintiffs hereby submit the following status report, pursuant to their earlier status report (ECF 75) and amended status report (76) and their letter motion (ECF 74) for a lifting of the stay in order to seek final injunctive relief against Rule 2.61.

As the Attorney General's Office advised the Court on May 31, 2023, Rule 2.61 is in the process of being repealed. We have learned that the public comment period for the proposed repeal expired on August 28, 2023. On August 28, 2023, I inquired of opposing counsel by email as to when the repeal, if it happens after public comment, will be published. The repeal would not be effective unless and until the Public Health and Health Planning Council approves it. I have not received a reply as to when that approval will occur.

Whether that approval happens remains in doubt from Plaintiffs' perspective. They are concerned about language in the State's Statement of Regulatory Impact (SRI) (attached) which appears to leave open the possibility of either a suspension versus an outright repeal of 2.61 or a new version of same under "evolving" requirements during the (seemingly endless) "course of COVID":

Needs and Benefits: COVID-19 vaccines are safe and effective, and COVID-19 vaccination offers the benefit of helping to reduce the number of COVID-19 infections.... However, federal recommendations for COVID-19 vaccination have changed and *are expected to evolve as the future course of COVID-19 becomes more apparent.* (emphasis added)

The State continues to maintain that COVID vaccines have been effective at preventing COVID infections when it is well established that they do no such thing. Moreover, the growing evidence of safety concerns, which clearly outweigh putative benefits for healthy people, continue to be ignored.

Plaintiffs' concern is further heightened by the SRI's statement regarding federal COVID vaccine requirements:

Federal Requirements: ... In light of these developments and comments received on the interim final rule, CMS has stated that it will soon end the requirement that covered providers and suppliers establish policies and procedures for staff vaccination, **which would bring the state and federal requirements into alignment.**

Plaintiffs believe this official attitude of parity with “evolving” federal requirements opens the way to reimposition of a mandate for a new vaccine for the latest in an endless series of variants, which is now being floated at the federal level under the rubric of “evolving” recommendations. In that regard, President Biden has requested Congressional funding for yet another “new vaccine” and the White House is being coy about whether it will be mandated for federal employees as opposed to “encouraged”—with “encouragement” having too often given way to ever-widening mandates over the past three years.¹

In view of these concerns, I further inquired of opposing counsel on August 28 “Whether the State of New York reserves the right to impose a new COVID vaccine mandate for health care workers whenever it deems such necessary or to bring New York into alignment with any new federal COVID vaccine mandate.” We have yet to receive a reply to that request.

For these reasons, Plaintiffs agree that this matter should abide a new status report on September 29, 2023, by which time, it is hoped, the parties will know whether the State is done, once and for all, with compelling health care workers to be vaccinated or lose their employment or hospital privileges. Failing that assurance, Plaintiffs expect to renew their request for a lifting of the stay and final injunctive relief under the leeway for that approach, based on changing facts, contemplated by the preliminary, non-merits decision in *We the Patriots*.

Respectfully submitted,

s/Christopher A. Ferrara
Christopher A. Ferrara
(N.D.N.Y. Bar No. 51198)
Senior Counsel-Thomas More Society
148-29 Cross Island Parkway
Whitestone, Queens, New York
11357 Telephone: 718-357-1040
cferrara@thomasmoresociety.org

c: All counsel of record (via ECF)

¹ See <https://www.foxnews.com/politics/biden-administration-will-encourage-americans-to-get-new-covid-19-vaccine-kjp-says>

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Public Health Law Sections 225, 2800, 2803, 3612, and 4010, as well as Social Services Law Sections 461 and 461-e, Title 10 (Health) and Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 2.61 of Title 10 is repealed.

Subparagraph (vi) of paragraph (10) of subdivision (b) of Section 405.3 of Part 405 of Title 10 is repealed.

Paragraph (5) of subdivision (a) of Section 415.19 of Part 415 of Title 10 is repealed.

Paragraph (7) of subdivision (d) of Section 751.6 of Title 10 is repealed.

Paragraph (6) of subdivision (c) of Section 763.13 of Title 10 is repealed.

Paragraph (7) of subdivision (d) of Section 766.11 of Title 10 is repealed.

Paragraph (8) of subdivision (d) of Section 794.3 of Title 10 is repealed.

Paragraph (5) of subdivision (q) of Section 1001.11 of Title 10 is repealed.

Paragraph (18) of subdivision (a) of Section 487.9 of Title 18 is repealed.

Paragraph (14) of subdivision (a) of Section 488.9 of Title 18 is repealed.

Paragraph (15) of subdivision (a) of Section 490.9 of Title 18 is repealed.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) Sections 225(5), 2800, 2803(2), 3612 and 4010(4) authorize the Public Health and Health Planning Council (PHHPC) and Commissioner to promulgate regulations: amending the State Sanitary Code; implementing the purposes and provisions of PHL Article 28; with respect to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies; and with respect to hospice organizations.

Social Service Law (SSL) Section 461 authorizes the Department of Health (Department) to promulgate regulations establishing general standards applicable to Adult Care Facilities (ACF).

Legislative Objectives:

The legislative objective of PHL Section 225 empowers PHHPC to address any issue affecting the security of life or health or the preservation and improvement of public health in the state of New York, including designation and control of communicable diseases and ensuring infection control at healthcare facilities and any other premises. PHL Article 28 specifically addresses the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. PHL Article 36 addresses the services rendered by certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies. PHL

Article 40 declares that hospice is a socially and financially beneficial alternative to conventional curative care for the terminally ill. Lastly, the legislative objective of SSL Section 461 is to promote the health and well-being of residents of ACFs.

Needs and Benefits:

COVID-19 vaccines are safe and effective, and COVID-19 vaccination offers the benefit of helping to reduce the number of COVID-19 infections. The State's regulation requiring covered entities to ensure that personnel are fully vaccinated against COVID-19, has increased the percentage of health care workers who are vaccinated against COVID-19.

However, federal recommendations for COVID-19 vaccination have changed and are expected to evolve as the future course of COVID-19 becomes more apparent. Additionally, there are now effective treatments for COVID-19, case rates appear to have steadily declined, and hospitalizations due to COVID-19 have substantially decreased.

In response to changes in federal recommendations for COVID-19 vaccination and the overall pandemic landscape, the proposed regulation would repeal the requirement that covered entities ensure that personnel are fully vaccinated against COVID-19, as well as repeal the requirement that covered entities document evidence thereof in appropriate records. In lieu of a regulation, covered entities may now individually consider how to implement their own internal policies regarding COVID-19 vaccination, provided they remain in compliance with other applicable state and federal laws and regulations.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The proposed regulation does not impose any new costs to regulated entities.

Cost to State and Local Government:

The proposed regulation does not impose any new costs to the State or local governments.

Cost to the Department of Health:

There are no additional costs to the State or local government but there may be modest costs savings, since the State and local governments will no longer need to perform surveillance of regulated parties to monitor compliance with the requirement that personnel be fully vaccinated against COVID-19.

Local Government Mandates:

There is no impact on local government mandates associated with this proposed rule change.

Paperwork:

No new paperwork is necessitated by the proposed regulation.

Duplication:

This regulation will not conflict with any state or federal rules.

Alternative Approaches:

One alternative the Department considered was to amend the regulation to require personnel to be “up to date” on COVID-19 vaccinations, rather than “fully vaccinated.” However, this option was not considered viable because of the likelihood of continued changes to federal COVID-19 vaccine recommendations and the language surrounding those recommendations. Another alternative that was considered was to allow personnel to wear a well-fitting face covering in lieu of being vaccinated. However, this option was ultimately not chosen because of unknowns surrounding future trends in COVID-19 case rates and because of the likely continuing evolution of federal vaccine recommendations.

Federal Requirements:

On November 5, 2021, the U.S. Department of Health and Human Services’ Centers for Medicare & Medicaid Services (CMS) issued an interim final rule (CMS-3415-IFC) requiring Medicare and Medicaid-certified providers and suppliers to ensure that their staff were fully vaccinated for COVID-19 (i.e., obtain the primary vaccination series). On April 10, 2023, the President signed legislation that ended the COVID-19 national emergency and subsequently on May 11, 2023, the COVID-19 public health emergency expired. In light of these developments and comments received on the interim final rule, CMS has stated that it will soon end the requirement that covered providers and suppliers establish policies and procedures for staff vaccination, which would bring the state and federal requirements into alignment.

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. Effective immediately the Department will cease citing providers for failing to comply with the requirements of 10 NCYRR Section 2.61 while the regulation is in the process of being repealed. The Department may, however, continue to seek sanctions against providers based on previously cited violations that allegedly occurred.

Contact Person:

Ms. Katherine E. Ceroalo
NYS Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, NY 12237
(518) 473-7488
(518) 473-2019 –FAX
REGSQNA@health.ny.gov

**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not required because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not necessary because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.